UNITED STATES DEPARTMENT OF COMMERCE
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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
07/117,823	11/09/87	ZUGLIOTTI	A

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EXAMINER	
NORTHINGTON	
ART UNIT	**PAPER NUMBER**
111	3

DATE MAILED: 03/11/88

3/11/88

This is a communication from the examiner in charge of your application.

COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire three month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449
4. ☐ Notice of informal Patent Application, Form PTO-152
5. ☐ Information on How to Effect Drawing Changes, PTO-1474
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☒ Claims 1-10 are pending in the application.
   Of the above, claims 2-7 are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1, 8, 9, and 10 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings which are acceptable for examination purposes until such time as allowable subject matter is indicated.
8. ☐ Allowable subject matter having been indicated, formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. These drawings are ☐ acceptable; ☐ not acceptable (see explanation).
10. ☐ The ☐ proposed drawing correction and/or the ☐ proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved. ☐ disapproved (see explanation). However, the Patent and Trademark Office no longer makes drawing changes. It is now applicant's responsibility to ensure that the drawings are corrected. Corrections MUST be effected in accordance with the instructions set forth on the attached letter "INFORMATION ON HOW TO EFFECT DRAWING CHANGES", PTO-1474.
12. ☒ Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☑ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

Restriction is required to one of the following inventions according to 35 USC 121.

GROUP I: Claim 1 (part), drawn to compounds wherein X represents O or S, classified in 544/59,106 and 514/222 and 227.

GROUP II: Claim 1 (part), drawn to compounds wherein X represents N, classified in 544/336 and 514/255.

GROUP III: Claim 1 (part), drawn to compounds wherein X represent $(CH_2)m$ and m=0, 1, or 2, classified in 540/609, 546/248, 548/570 and 514/212, 315 and 428.

GROUP IV: Claims 2-7, drawn to a process of preparing compounds of formula I.

The inventions are distinct, each from the other, because of the following reasons:

The aromatic rings within the definition of formula I are so diverse in scope, that a prior art reference anticipating the claims under 34 USC 102 with respect to one member of the X moiety, would not render obvious the same claim under 35 USC 103 with respect to another member.

Inventions I-III and IV are related as process of making and product made.

The inventions are distinct if either (1) the process as claimed can be used to make another and materially different product, or (2) the product as claimed can be made by another and materially different process. MPEP 806.05(f).

In this case, the product as claimed can be made by

a materially different process such as the process disclosed in U.S. Patent No. 3,558,690.

The compounds of the invention can be prepared by three different processes. See Columns 5-7.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and their recognized divergent subject matter restriction for examination purposes as indicated is proper.

Additionally, composition will be examined along with Group I, II, or III and should be commensurate in scope with the elected invention.

During a telephone conversation with Mr. Jim Lydon on February 24, 1988 a provisional election was made with traverse to prosecute the invention of Group III, claims 1 and 8-10 (part). Affirmation of this election must be made by applicant in responding to this Office action. Claims 2-7 are withdrawn from further consideration by the examiner as being drawn to a nonelected invention. See 37 CFR 1.142(b).

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having

ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1, 8, 9, and 10 are rejected under 35 U.S.C. 103 as being unpatentable over Sallmann et al.

The instantly claimed diclofenac salt with a heterocyclic base is taught by Sallmann et al. See Column 4, lines 33-34, respectively.

Furthermore, the addition of an inert carrier does not render an otherwise obvious compound patentable. See In re Pearson, 181 USPQ 641 and In re Juominen, 213 USPQ 89.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless-

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102b as being clearly anticipated by Sallmann et al.

The instantly claimed diclofenac salt with piperidino-ethanol is disclosed by Sallmann et al. See

Column 4, line 34, respectively.

Claims 8, 9, and 10 are rejected under 35 U.S.C. 112, first and second paragraphs, as the claimed invention is not described in such full, clear, concise and exact terms as to enable any person skilled in the art to make and use the same, and/or for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The said claims are non-limiting by the recitation of the term "containing" which implies a composition with other ingredients which are not specified.

The term "characterized" is indefinite.

The recitation of the phrase "to form a solutions" is unclear. Clarification is required.

A pharmaceutical composition should recite an intended use.

Receipt is acknowledged of papers submitted under 35 U.S.C. 119, which papers have been placed of record in the file.

Any inquiry concerning this communication should be directed to Zinna Northington at telephone number 703-557-8871.

Northington:meb

3/8/88:Retype 3/10/88

JOHN M. FORD
EXAMINER
GROUP ART UNIT 121